RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1-31 were pending at the time of the Action. Claims 4 and 26 have been canceled herein. Claims 1-3, 5-25 and 27-31 are now pending and presented for reconsideration.

B. Claims Objection

The Action objected to claim 26 as being in improper dependent form. Applicants note that the claim has been canceled herein and thus the objection is now moot.

C. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

The Action rejects claims 2-4, 14-20 and 27-30 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out the subject matter which Applicant regards as the invention.

(1) Rejection of claim 2

The Action rejects claim 2 taking the position that "population of seed of the corn variety I390186" is unclear on the basis that an express definition is not provided for "population" and based on a citation the Examiner makes to a particular use of the term. In response, Applicants note that the term "population" has a well known meaning in the art and thus the use of the term in the claims is not indefinite. Claims must be given their plain meaning and limitations from the specification are not read into a claim. Provided herewith as evidence of the well known meaning of "population," a copy of the definition for this term from the on-line version of the Merriam-Webster™ dictionary is given at **Exhibit A**. The term is therefore fully definite and removal of the rejection is respectfully requested.

(2) Rejection of claims 3-4

Claims 3-4 are rejected as allegedly broadening the claims from which they depend. Claim 4 has been canceled and thus the rejection of this claim is now moot. With respect to claim 3, it is noted that the claim does not broaden the scope of the claim from which it depends, claim 2. As indicated above, claim 2 reads as follows:

> 2. A population of seed of the corn variety I390186, wherein a sample of the seed of the corn variety I390186 was deposited under ATCC Accession No. PTA-4491.

Claim 3 recites the population of seed of claim 2, "further defined as an essentially homogeneous population of seed." Claim 3 thus further defines the population of claim 2 as being "essentially homogeneous." While claim 2 is directed to a population of seed of the corn variety I390186, it is not necessary that the population be an essentially homogeneous population of seed. A population may be other than essentially homogeneous yet still be a population. For example, the relevant definition of "population" from the on-line version of the Merriam-Webster™ dictionary is "a body of persons or individuals having a quality or characteristic in common." **Exhibit A**. In contrast, the definition for "homogeneous" from the same on-line dictionary is given as "of uniform structure or composition throughout." **Exhibit B**. Therefore a collection of seed may at the same time have a quality or characteristic in common, *e.g.*, be of variety I390186, yet not be of uniform structure or composition throughout. For example, a population of seed of corn variety I390186 could be non-uniform in size or shape, due to growth or other conditions, yet still have the common quality of being a corn plant of variety I390186. As such, claim 3 is in proper dependent form and is not indefinite. Removal of the rejection is thus respectfully requested.

(3) Rejection of claim 14

The rejection of claim 14 has also been maintained for reciting the term "essentially homogeneous population." Claim 14 reads as follows:

> 14. An essentially homogeneous population of corn plants produced by growing the seed of the corn variety I390186, wherein a sample of the seed of the corn variety I390186 was deposited under ATCC Accession No. PTA-4491.

Applicants again note that, as set forth above, a population need not be essentially homogeneous, whether a population of plants or seeds. Further defining a population as essentially homogeneous does not render the claim indefinite. A population of plants grown from the seed of corn variety I390186 could vary in size or other characteristics due to environmental or other conditions, but still constitute a population of corn plant produced by growing the seed of corn variety I390186. As such, "essentially homogeneous" further defines the scope of the claim and the term as it is used is not indefinite. Removal of the rejection is thus respectfully requested.

(4) Rejection of claims 15, 17 and 20

The Action rejects claim 15, 17 and 20 as being indefinite for reciting "capable of expressing." In response, it is noted that the claims have been amended and thus it is believed that the rejection is now moot.

(5) Rejection of claims 16 and 27

The Action rejects the claims as allegedly broadening the scope of the claims from which they depend. It is in particular stated that the claims "add on a gene and trait to the plant of their parent claims" and that there is no indication how the plants acquired the gene and that the gene is not possessed by the plant of the parent claims.

Applicants do not understand the rejection. As stated in both sentences explaining the rejection, the claims further narrow the claim from which they depend because the claims specify

a further limitation ("add on a gene"), and the limitation is not possessed by the parent claims. Specifically, claims 16 adds "a nuclear or cytoplasmically-inherited gene conferring male sterility," while claim 27 adds "a single locus conversion," neither element of which is required by the main claim. Therefore, both claims (1) ***contain a reference to parent claim*** from which they depend, (2) contain a ***further limitation*** of the subject matter claimed in the main claim, and (3) ***incorporate all elements*** of the claim from which they depend. The claims are therefore in proper dependent form pursuant to 37 C.F.R. §1.75(c) and are fully definite. As to how the plants acquire the added elements, this is irrelevant to the scope or definiteness of the claims, as the claims are product claims, not process or product by process claims.

(6) Rejection of claim 28

The Action states that claim 28 is indefinite because the article" a" in the recitation "wherein the single locus was stably inserted into a corn genome" renders the claim indefinite because it is not clear if it was inserted into the genome of I390186 or that of a different plant. Applicants traverse.

The single locus referred to in claim 28 may or may not have been inserted into the genome of I390186. This does not render the claim indefinite, however. The claim specifies that the single locus was stably inserted into a corn genome. Loci that are stably inserted into a corn genome are also stably inherited. Thus the single locus need not have been inserted into the genome of corn variety I390186. As such, the metes and bounds of the claim are clear and the claim is not indefinite.

D. **Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Written Description**

The Action rejects claims 2-4, 14 and 24-31 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to convey that Applicants were in possession of the claimed invention. Applicants respectfully traverse as set forth below.

(1) Populations and essentially homogeneous populations of seed of variety I390186 in claims 2 and 3 and populations of plants grown therefrom recited in claim 14 have been fully described.

With regard to claim 2, Applicants first note that a population of seeds of corn variety I390186 has been deposited with the ATCC. The claimed population is therefore fully described. With respect to claim 3, further describing the population of claim 3 as an "essentially homogeneous population" of seed of corn variety I390186, Applicants again note that a population need not be essentially homogeneous. As set forth above, the relevant definition of "population" from the on-line version of the Merriam-Webster™ dictionary is "a body of persons or individuals having a quality or characteristic in common." **Exhibit A**. In contrast, the definition for "homogeneous" from the same on-line dictionary is given as "of uniform structure or composition throughout." **Exhibit B**. Therefore a collection of seed may at one time have a quality or characteristic in common, *e.g.*, be of variety I390186, yet not be of uniform structure or composition throughout. For example, a population of seed of corn variety I390186 could be non-uniform in size or shape, due to growth or other conditions, yet still have the common quality of being a corn plant of variety I390186.

Claim 3 is thus a proper dependent claim further narrowing claim 2. Given the description of the subject matter of claim 2, which was deposited with the ATCC, claim 3 is fully described. Claim 14 is similarly directed to an essentially homogeneous population of corn

plants produced by growing the seed of the corn variety I390186, and is therefore also described. Removal of the rejections is thus respectfully requested.

(2) Hybrid plants and seeds recited in claims 24-25 have been fully described

Rejected claims 24-25 are directed to hybrid plants and seeds produced with corn plant I390186 as one parent. With regard to claim 26, this has been cancelled herein as duplicative of the claim from which it depended. Applicants have fully described the claimed subject matter in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. As set forth in the breeding history at page 26 of the specification, corn plant I390186 is an inbred corn plant. All of the claimed hybrid plants having I390186 as a parent will therefore contain a copy of the same genome as corn plant I390186. That is, because I390186 is an inbred corn plant, hybrid corn plants derived therefrom will have as half of their genetic material the same genetic contribution of corn plant I390186, save the possibility of the rare spontaneous mutation or undetected segregating locus. This entire genetic contribution of corn plant I390186 is described in the specification by way of the deposit of seed of corn plant I390186 with the ATCC. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002) (holding that a biological deposit constitutes a written description of the deposited material under 35 U.S.C. §112, first paragraph). This represents a description of concrete and identifiable structural characteristics defining the claimed hybrid plants and distinguishing them from other plants in full compliance with the written description requirement.

The Federal Circuit has noted that such shared identifiable structural features are important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any

structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of the members of the claimed genus of hybrids having I390186 as one parent share the structural feature of having the genetic complement of I390186. One of skill in the art could thus readily identify the members of the genus. The written description requirement has, therefore, been fully complied with.

a. The shared characteristics of the claimed hybrid plants are readily identified and described in the specification

As set forth above, the claimed F1 hybrid plants having I390186 as one parent will share the genetic complement received from I390186. This is readily identifiable by genetic marker analysis, as shown in Tables 6 and 8 of the specification. There shown is the SSR genetic marker profile of corn variety I390186, as well as an the exemplary hybrid plant designated 0004411 that was made using I390186 as one parent. As can be seen, hybrid corn plant 0004411 has the SSR genetic marker profile of I390186, and also includes the genetic markers from the second parent plant used to make the hybrid. The same will be true for any other hybrid plant having I390186 as one parent, save for an occasional difference at a locus due to spontaneous genetic rearrangements, which occur at statistically insignificant frequencies in essentially all organisms.

The second plant that is used to make the claimed hybrid plants is irrelevant, as a hybrid will be produced any time corn plant I390186 is crossed with a second plant. That is, any second plant capable of reproduction may be used to make the hybrid plant. Applicants cannot therefore be said to lack written description for the second genetic complement. This is particularly so given that hundreds or even thousands of different inbred corn lines were well known to those of

skill in the art prior to the filing of the instant application, each of which could be crossed to make a hybrid plant within the scope of the claims. This is evidenced by a review of the U.S.P.T.O. patent data website, which reveals utility patents issued on hundreds of different corn varieties. For example, a search of patents including "inbred corn line" in the title reveals more than 195 patents issued for corn varieties prior to the filing date of the current application; and a search for patents having "inbred maize line" in the title reveals more than 120 patents issued prior to the filing date. Any one of these corn plants, or the many hundreds or thousands of other maize plants that were known at the time the application was filed, could be used to produce an F1 hybrid plant having corn variety I390186 as one parent, and each of these would share the genetic complement of I390186.

Written description must be reviewed from the perspective of one of skill in the art at the time the application is filed. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). The specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). As *any* second plant may be used to produce the claimed hybrid plants and such plants were well known to those of skill in the art, applicants cannot be said to have not been in possession of the second parent plant. The claimed hybrid corn plants have therefore been described in compliance with 35 U.S.C. §112, first paragraph.

The Action attempts to downplay the significance of the genetic marker data given in the specification by stating that some loci may be shared by other plants, that primer sequences are not described or that certain isozyme markers are not informative. However, no effort has been made to show that any substantial number of marker loci actually *are* shared by other plants. Further, Applicants do not claim such "other" plants, so this is irrelevant to written description.

No basis has been provided to conclude that the claimed hybrid plants are not distinct and clearly identifiable by the genetic marker profile that has been set forth. Regarding the availability of genetic markers, the service that was used to detect SSR markers is commercially available to the public. Further, SSR and any of the other genetic marker systems that are well known to those of skill in the art may potentially be used, as is described on pages 59-60 of the specification. Regardless of whether SSR markers are used, the shared genetic complement of the claimed hybrid plants having corn variety I390186 as one parent distinguishes them. As the entire genome of corn variety I390186 has been described, at least, by way of the seed deposit that has been made, any polymorphic locus could be used including or in addition to the SSR markers shown in Tables 6 and 8.

b. The Action's allegations that the expression of the genetic complement of corn variety I390186 is unpredictable are inapposite

The Action alleges that claimed hybrid plants have not been described despite inheriting the genetic complement of variety I390186 because information is not provided regarding the morphological and physiological traits of the hybrid plants. It is alleged that how the genes that are inherited would be expressed or would interact has not been shown. However, this misses the point that applicants have gone one step further than morphological and physiological traits by describing the claimed hybrid plants at the most basic structural level, the genome. A better description could not be made. Morphological and physiological traits, while helpful, are also subject to environmental variation and require subjective gradations. Genetic testing goes to the source of traits and yields concrete values.

The law further makes no distinctions regarding the manner in which applicants choose to describe claimed compositions. Rather, an applicant must merely describe the claimed subject

matter by "whatever characteristics sufficiently distinguish it." *Amgen v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Here, Applicants have described the genetic complement of parent plant I390186 that will be comprised in the claimed hybrid plants. This has been achieved using the SSR and isozyme genetic marker profiles given in tables 6-9 of the specification. Indeed, applicants describe the entire genetic complement of parent plant I390186 by way of a seed deposit made with the ATCC. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1330 (Fed. Cir. 2002). As such, any of the many well known marker systems may be used to readily detect and identify any of the claimed hybrids produced having variety I390186 as one parent.

c. Applicants fully describe an exemplary hybrid made using inbred I390186

Further description of claimed hybrid plants is also provided in the specification by way of a detailed description of hybrid 0004411, which was produced with I390186 as one inbred parent. This plant is representative of hybrids produced using I390186 as one parent, each of which comprise the genetic complement of the parent corn plant as set forth above. Table 4 of the specification gives the performance characteristics for 0004411 and provides comparisons against other hybrid varieties. In Table 4, the morphological traits of 0004411 are given. The SSR and isozyme marker profiles for hybrid 0004411 are given in Tables 8 and 9, respectively. This information, combined with the descriptions of I390186 in the specification and the shared structure among hybrids having corn plant I390186 as a parent, is more than adequate to describe the claimed subject matter.

(3) Single locus converted plants of corn variety I390186 in claims 27-30 have been fully described

The Action has maintained the rejection of claims 27-30, which are directed to a single locus conversion of corn plant I390186. In particular, the Action has alleged that: (1) the characteristics of the claimed single locus converted plant are unpredictable and/or not described, (2) the claims encompass genes that have yet to be discovered, and (3) the sequences and/or sources for the numerous examples of single locus traits disclosed in the application have not been described.

a. The claimed subject matter is not unpredictable

With regard to the first point made by the Action, it is noted that a "single locus converted (conversion) plant" is defined at page 23, lines 6-12 of the specification as follows:

> [p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred *via* the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Therefore, the claimed plants comprising a single locus conversion possess "essentially all of the desired morphological and physiological characteristics of [the single gene converted plant]". The Action's comments with regard to various allegedly unknown characteristics are thus outside the scope of the claims. With regard to the claimed subject matter, Applicants have more than adequately described such a plant that comprises essentially all of the desired morphological and physiological characteristics of corn plant I390186 by way of the description and deposit of I390186 alone, not to mention other description provided. To hold otherwise would be to limit Applicants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012, 10

USPQ2d 1614, 1618 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)) .

b. The rejection has been applied with respect to unclaimed subject matter

With respect to the Action's allegation that the claims encompass genes that have yet to be discovered, it is noted that Applicants ***do not claim undiscovered genes***. The claimed subject matter is the corn variety I390186 comprising a single locus conversion. Any single locus conversion may be introduced into corn variety I390186 to produce the claimed single locus conversion. The fact that a given gene could be isolated in the future and introduced as a single locus conversion is irrelevant – the new gene is not claimed *per se*, a single locus conversion of corn plant I390186 is claimed. Under the reasoning of the Action, essentially any claim could be read to encompass subject matter yet to be invented and therefore not be described. A claim to a corn plant transformed with a particular gene would be invalid because it would encompass corn varieties yet to be discovered. A claim to a given gene operably linked to a regulatory element would be invalid because as yet to be isolated regulatory elements would be encompassed. Nearly any biotechnological invention could be viewed this way applying the Action's reasoning. However, it is not any given single locus that is claimed, it is a corn plant of corn variety I390186 which comprises a single locus that has been claimed. The claimed subject matter is thus fully described.

c. Applicants have disclosed numerous single locus traits and these traits were well known to those of skill in the art when the application was filed

The Action alleges that the traits recited in the application and referred to in Applicants previous response to office action have not been shown to have been known in the art. The

Action has therefore invited Applicants to amend the claims to recite individual examples of single locus traits. However, Applicants' previous evidence submitted in the prior response to office action showed numerous single locus traits.

Among just the examples in the specification recited with a publication reference or patent number are the following (see specification at pages 29-34): genes conferring male sterility (U.S. Patent No. 3,861,709, U.S. Patent No. 3,710,511, U.S. Patent No. 4,654,465, U.S. Patent No 5,625,132, and U.S. Patent No. 4,727,219, incorporated by reference); male-sterility restorer genes (U.S. Patent Nos. 5,530,191, 5,689,041, 5,741,684, and 5,684,242, incorporated by reference); a herbicide resistant EPSPS mutation termed *aroA* (U.S. Patent 4,535,060); and a mutant maize gene encoding a protein with amino acid changes at residues 102 and 106 (PCT Publication WO 97/04103).

The single locus traits are also described by way of PCT Application Publ. WO 95/06128, which was specifically incorporated by reference at page 31 of the specification. Examples of some of the single locus traits described in WO 95/06128, including any associated phenotype and publication reference given, are the following:

the uidA gene from *E. Coli* encoding β-glucuronidase (GUS) (cells expressing *uidA* produce a blue color when given the appropriate substrate, Jefferson, R.A. 1987. *Plant Mol. Biol. Rep* 5: 387-405); the *bar* gene from *Streptomyces hygroscopicus* encoding phosphinothricin acetyltransferase (PAT) (cells expressing PAT are resistant to the herbicide Basta, White, J., Chang, S.-Y.P., Bibb, M.J., and Bibb, M.J. 1990. *Nucl. Ac. Research* 18: 1062); the *lux* gene from firefly encoding luciferase (cells expressing *lux* emit light under appropriate assay conditions, deWet, J.R., Wood, K.V., DeLuca, M., Helinski, D.R., Subramani, S. 1987. *Mol. Cell. Biol.* 7: 725-737); the *dhfr* gene from mouse encoding dihydrofolate reductase (DHFR) (cells expressing *dhfr* are resistant to methotrexate; Eichholtz, D.A., Rogers, S.G., Horsch, R.B., Klee, H.J., Hayford, M., Hoffman, N.L., Bradford, S.B., Fink, C., Flick, J., O'Connell, K.M., Frayley, R.T. 1987. *Somatic Cell Mol. Genet.* 13: 67-76); the *neo* gene from *E.Coli* encoding aminoglycoside phosphotransferase (APH) (cells expressing *neo* are resistant to the aminoglycoside antibiotics; Beck, E., Ludwig, G., Auerswald, E.A., Reiss, B., Schaller, H. 1982. *Gene* 19: 327-336); the *amp* gene from *E. Coli* encoding β-lactamase (cells expressing β-lactamase produce a chromogenic compound when given the appropriate substrate; Sutcliffe,

J.G. 1978. *Proc. Nat. Acad. Sci.* USA 75: 3737-3741); the *xylE* gene from *Ps. putida* encoding catechol dihydroxygenase (cells expressing *xylE* produce a chromogenic compound when given the appropriate substrate; Zukowsky *et al.* 1983. *Proc. Nat. Acad. Sci.* USA 80: 1101-1105); the R,C1 and B genes from maize encode proteins that regulate anthocyanin biosynthesis in maize (Goff, S., Klein, T., Ruth, B., Fromm, M., Cone, K., Radicella, J., Chandler, V. 1990. *EMBO J.:* 2517-2522); the ALS gene from *Zea mays* encoding acetolactate synthase and mutated to confer resistance to sulfonylurea herbicides (cells expressing ALS are resistant to the herbicide; Gleen. Yang, L.Y., Gross, P.R., Chen, C.H., Lissis, M. 1992. *Plant Molecular Biology* 18: 1185-1187); the proteinase inhibitor II gene from potato and tomato (plants expressing the proteinase inhibitor II gene show increased resistance to insects; potato - Graham, J.S., Hall, G., Pearce, G., Ryan, C.A. 1986 *Mol. Cell. Biol.* 2: 1044-1051; tomato - Pearce, G., Strydom, D., Johnson, S., Ryan, C.A. 1991. *Science* 253: 895-898); the *Bt* gene from *Bacillus thuringensis* berliner 1715 encoding a protein that is toxic to insects (this gene is the coding sequence of *Bt* 884 modified in two regions for improved expression in plants; Vaeck, M., Reynaerts, A., Hofte, H., Jansens, S., DeBeuckeleer, M., Dean, C., Aeabeau, M., Van Montagu, M., and Leemans, J. 1987. *Nature* 328: 33-37); the *bxn* gene from *Klebsiella ozaeneae* encoding a nitrilase enzyme specific for the herbicide bromoxynil (cells expressing this gene are resistant to the herbicide bromoxynil; Stalker, D.m., McBride, K.E., and Malyj, L. *Science* 242: 419-422, 1988); the WGA-A gene encoding wheat germ agglutinin (expression of the WGA-A gene confers resistance to insects; Smith, J.J., Raikhel, N.V. 1989. *Plant Mol. Biology* 13: 601-603); the *dapA* gene from *E. coli* encoding dihydrodipicolinate synthase (expression of this gene in plant cells produces increased levels of free lysine; Richaud, F., Richaud, C., Rafet, P. and Patte, J.C. 1986. *J. Bacteriol.* 166: 297-300); the *Z10* gene encoding a 10kd zein storage protein from maize (expression of this gene in cells alters the quantities of 10kD Zein in the cells; Kirihara, J.A., Hunsperger, J.P., Mahoney, W.C., and Messing, J. 1988. *Mol. Gen. Genet.* 211: 477-484); the Bt gene cloned from *Bacillus thuringensis* Kurstaki encoding a protein that is toxic to insects (the gene is the coding sequence of the cry IA(c) gene modified for improved expression in plants - plants expressing this gene are resistant to insects; Höfte, H. and Whiteley, H.R., 1989. *Microbiological Reviews.* 53: 242-255); the ALS gene from *Arabidopsis thaliana* encoding a sulfonylurea herbicide resistant acetolactate synthase enzyme (cells expressing this gene are resistant to the herbicide Gleen. Haughn, G.W., Smith, J., Mazur, B., and Somerville, C. 1988. *Mol. Gen. Genet.* 211: 266-271); the *dehl* gene from *Pseudomonas putida* encoding a dehalogenase enzyme (cells expressing this gene are resistant to the herbicide Dalapon; Buchanan-Wollaston, V., Snape, A., and Cannon, F. 1992. *Plant Cell Reports* 11: 627-631); the hygromycin phosphotransferase II gene from *E. coli* (expression of this gene in cells produces resistance to the antibiotic hygromycin. Waldron, C., Murphy, E.B., Roberts, J.L., Gustafson, G.D., Armour, S.L., and Malcolm, S.K. *Plant Molecular Biology* 5: 103-108, 1985); the *mtlD* gene cloned from *E. coli* (the gene encodes the enzyme mannitol-1-phosphate dehydrogenase; Lee and Saier, 1983. *J. of Bacteriol.* 153:685); the HVA-1 gene encoding a Late Embryogenesis Abundant (LEA) protein (the gene was isolated from barley; Dure, L., Crouch, M., Harada, J., Ho, T.-H. D. Mundy, J., Quatrano, R, Thomas, T, and Sung, R., *Plant Molecular Biology* 12: 475-486.

The foregoing represent just some of the single locus coding sequences that were known as of March 2, 1995; ***nearly six years prior*** to the filing of the instant application. More than 25 regulatory elements were also described therein, as were numerous transformation vectors comprising combinations of these elements. Applicants could describe many more examples of single locus traits that were well known as of the filing date, and would be glad to do so should the Examiner find it useful. It thus goes without saying that single locus traits were more than well known to those of skill in the art as of the filing date and were fully described in the specification.

Techniques for the introduction of single locus traits by genetic transformation were further well known to those of skill in the art. Some of the transformation methods for corn that were well known as of the filing date and cited in the specification include the following: electroporation (U.S. Patent No. 5,384,253), microprojectile bombardment (U.S. Patent No. 5,550,318; U.S. Patent No. 5,736,369, U.S. Patent No. 5,538,880; and PCT Publication WO 95/06128), *Agrobacterium*-mediated transformation (U.S. Patent No. 5,591,616 and E.P. Publication EP672752), direct DNA uptake transformation of protoplasts (Omirulleh *et al.*, 1993) and silicon carbide fiber-mediated transformation (U.S. Patent No. 5,302,532 and U.S. Patent No. 5,464,765). Introduction of such traits by conventional breeding was also known. In fact, this is one of the most fundamental procedures in agricultural science, and it has not been alleged that this has not been described.

Applicants have therefore shown possession of the claimed single locus conversions. Both large numbers of single locus traits and the associated phenotypes were well known to those of skill in the art. The specification itself defines a single locus converted plant as comprising essentially all of the desired morphological and physiological characteristics of the starting non-

converted plant, *e.g.*, I390186. Well more than an adequate number of examples have been provided and were known in the art to satisfy written description. The state of the art must be considered in the written description determination. As such, Applicants respectfully request removal of the rejection.

(4) The rejection of claim 31 is improper

The Action has maintained the rejection of claim 31. The claim reads as follows:

31. A method of producing an inbred corn plant derived from the corn variety I390186, the method comprising the steps of:

(a) preparing a progeny plant derived from corn variety I390186 by crossing a plant of the corn variety I390186 with a second corn plant, wherein a sample of the seed of the corn variety I390186 was deposited under ATCC Accession No. PTA-4491;

(b) crossing the progeny plant with itself or a second plant to produce a seed of a progeny plant of a subsequent generation;

(c) growing a progeny plant of a subsequent generation from said seed and crossing the progeny plant of a subsequent generation with itself or a second plant; and

(d) repeating steps (b) and (c) for an addition 3-10 generations to produce an inbred corn plant derived from the corn variety I390186.

It is believed that the rejection is made based on the position that each product produced at any intermediate or penultimate step of the method must be described as if claimed *per se*. It is respectfully submitted that this is a misstatement of the law. What is required to meet the written description requirement is that an Applicant show that he or she was in possession of the ***claimed invention***. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Here, a process is claimed, not a product of a process, and thus the steps of that process must be described, not intermediate or final products of the steps. The starting materials for the process must also be provided, otherwise the process could not be completed. However, the only starting materials required are corn variety I390186, which the Action does not allege to have not been described, and ***any*** second corn plant. As set forth above, corn plants were well known, and this has also therefore been fully described.

With respect to the steps, these have been fully set forth in the claim. It has not been alleged that any essential steps are absent. All that is required to complete the claimed method is to cross the corn variety I390186 or a product that is produced by any preceding step according to the steps given. All of the starting materials for any step within the method are either (1) corn variety I390186, (2) any second corn plant, or (3) a corn plant that is produced by following a preceding method step. The method has therefore been fully described.

It is also noted that corn breeding is well known to those of skill in the art. Without it, there would not be commercial corn varieties, which are typically sold as hybrids produced by crossing two inbred varieties. This is evidenced by the more than 300 issued patents to inbred maize varieties discussed above, given that inbred plants are not produced without multiple generations of intentional self-fertilization breeding steps. All of the steps recited in claim 31 are typical of the process used for the production of new corn varieties, save for the point of novelty, corn variety I390186. This is evidenced in the breeding history for the production of corn variety I390186, which is given in the specification. The specification also describes methods and considerations for producing new corn varieties in the review of related art, for example, at pages 2-4 of the application.

In conclusion, all steps of the claimed process have been recited, all starting materials have been fully described, and methods of producing new corn varieties were well known to those of skill in the art. Claim 31 has therefore been fully described in compliance with 35 U.S.C. §112, first paragraph. Removal of the rejection is thus respectfully requested.

E. **Rejection of Claims Under 35 U.S.C. §112, First Paragraph - Enablement**

The Action rejects claims 27-30 under 35 U.S.C. §112, first paragraph as allegedly not enabled. Applicants respectfully traverse.

The rejected claims are directed to corn plants of variety I390186 comprising a single locus conversion. In an attempt to support the rejection, the Action maintains recitation to several references alleged to show the difficulty of making male sterile or single locus converted plants. As noted before, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. The Action nonetheless states that these references show effects such as linkage drag, epistasis and linkage disequilibrium that "are not limited to just the plants exemplified in the cited references, and Applicant does not explain why these issues are not a concern [for] corn plants."

It appears that the Action has improperly placed the burden to show enablement on Applicants. The indication that the references concerning petunias, sugar beets and tomatoes applies to corn is made without any support. At the same time, the Action attempts to require applicants to show why this is not true. Applicants respectfully note that it is the *Office* the bears the burden of supporting its rejections. Findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act ("APA"). 5 U.S.C. § 706(A), (E), 1994; *see also In re Zurko,* 59 USPQ 2d 1693 (Fed. Cir. 2001). In particular, the Federal Circuit has held that findings by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record pursuant to the APA. *See In re Gartside*, 203 F.3d 1305, 1314-15 (Fed. Cir. 2000). Thus, an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be

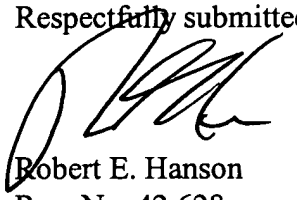
upheld by the Board of Patent Appeals and Interferences. The current rejections are unsupported as required by the APA. Removal of the rejection is thus respectfully requested.

F. Conclusion

This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicant submits that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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Date: September 30, 2003

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2 entries found for **population**.
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Main Entry: **pop·u·la·tion**
Pronunciation: `"pä-py&-'lA-sh&n`
Function: *noun*
Etymology: Late Latin *population-, populatio,* from Latin *populus*
Date: 1612
1 a : the whole number of people or inhabitants in a country or region **b :** the total of individuals occupying an area or making up a whole **c :** the total of particles at a particular energy level -- used especially of atoms in a laser
2 : the act or process of populating
3 a : a body of persons or individuals having a quality or characteristic in common **b** (1) **:** the organisms inhabiting a particular locality (2) **:** a group of interbreeding organisms that represents the level of organization at which speciation begins
4 : a group of individual persons, objects, or items from which samples are taken for statistical measurement
- **pop·u·la·tion·al** `/-shn&l, -sh&-n&l/` *adjective*

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Click on the example word to hear it pronounced.

\&\ as **a** and **u** in abut	\e\ as **e** in bet	\o\ as **aw** in law
\ᵊ\ as **e** in kitten	\E\ as **ea** in easy	\oi\ as **oy** in boy
\&r\as **ur/er** in further	\g\ as **g** in go	\th\ as **th** in thin
\a\ as **a** in ash	\i\ as **i** in hit	\th\ as **th** in the
\A\ as **a** in ace	\I\ as **i** in ice	\ü\ as **oo** in loot
\ä\ as **o** in mop	\j\ as **j** in job	\u\ as **oo** in foot
\au\ as **ou** in out	\[ng]\ as **ng** in sing	\y\ as **y** in yet
\ch\ as **ch** in chin	\O\ as **o** in go	\zh\ as **si** in vision

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One entry found for **homogeneous**.

Main Entry: **ho·mo·ge·neous**
Pronunciation: `-'jE-nE-&s, -ny&s`
Function: *adjective*
Etymology: Medieval Latin *homogeneus, homogenus,* from Greek *homogenEs,* from *hom-* + *genos* kind -- more at KIN
Date: 1641
1 : of the same or a similar kind or nature
2 : of uniform structure or composition throughout <a culturally *homogeneous* neighborhood>
3 : having the property that if each variable is replaced by a constant times that variable the constant can be factored out : having each term of the same degree if all variables are considered <a *homogeneous* equation>
- **ho·mo·ge·neous·ly** *adverb*
- **ho·mo·ge·neous·ness** *noun*

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